

EXACT-RX SODIUM SULFACETAMIDE AND SULFUR 10%/5% CLEANSER- sodium sulfacetamide, sulfur lotion

Exact-Rx, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click [here](#).

Exact-Rx SODIUM SULFACETAMIDE and SULFUR 10%/5% Cleanser

INDICATIONS: Sodium Sulfacetamide 10% and Sulfur 5% Cleanser

is indicated for the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

DIRECTIONS FOR USE: Wash affected area once or twice daily, or as directed by your physician. Avoid contact with eyes or mucous membranes. Wet skin and liberally apply to areas to be cleansed, massage gently into skin for 10-20 seconds working into a full lather, rinse thoroughly and pat dry. If drying occurs, it may be controlled by rinsing cleanser off sooner or using less often. **See package insert for complete product information.**

FOR EXTERNAL USE ONLY. NOT FOR INTRAVAGINAL OR OPHTHALMIC USE. (KEEP AWAY FROM EYES).

KEEP THIS AND ALL MEDICATION OUT OF REACH OF CHILDREN.

In case of accidental ingestion contact a poison control center immediately. Keep container tightly closed.

CONTRAINDICATIONS: Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is contraindicated in persons with known or suspected hypersensitivity to sulfonamides, sulfur or any other component of this preparation. Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is not to be used by patients with kidney disease.

CAUTION: If redness or irritation occurs, discontinue use.

Each gram of sodium sulfacetamide 10% and sulfur 5% cleanser contains 100 mg of sodium sulfacetamide and 50 mg of sulfur in a cleanser containing ammonium lauryl sulfate, butylated hydroxytoluene, cetyl alcohol, cocamidopropyl betaine, disodium EDTA, glycerin, glyceryl stearate SE, guar gum, methylparaben, PEG-100 stearate, propylene glycol, propylparaben, purified water, sodium thiosulfate, stearyl alcohol, triacetin.

Store at 20 to 25C (68 to 77F). See USP Controlled Room Temperature. Protect from freezing.

See bottle for lot number and expiration date

Manufactured in the U.S.A. for

Exact-Rx, Inc., Melville, NY 11747

Sodium Sulfacetamide 10% &
Sulfur 5% Cleanser

Rx Only

DESCRIPTION: Sodium sulfacetamide is a sulfonamide with

antibacterial activity while sulfur acts as a keratolytic agent. Chemically sodium sulfacetamide is N-[(4-aminophenyl)sulfonyl]-acetamide, monosodium salt, monohydrate. The structural formula is:
Each gram of sodium sulfacetamide 10% and sulfur 5% cleanser contains 100 mg of sodium sulfacetamide and 50 mg of sulfur in a cleanser containing butylated hydroxytoluene, cetyl alcohol, disodium EDTA, disodium oleamido MEA-sulfosuccinate, glyceryl stearate, magnesium aluminum silicate, methylparaben, PEG-100 stearate, petrolatum, propylene glycol, propylparaben, purified water, sodium cocoyl isethionate, sodium methyl cocoyl taurate, sodium thiosulfate, stearyl alcohol, xanthan gum.

CLINICAL PHARMACOLOGY: The most widely accepted mechanism of action of sulfonamides is the Woods-Fields theory which is based on the fact that sulfonamides act as competitive antagonists to para-aminobenzoic acid (PABA), an essential component for bacterial growth. While absorption through intact skin has not been determined, sodium sulfacetamide is readily absorbed from the gastrointestinal tract when taken orally and excreted in the urine, largely unchanged. The biological half-life has variously been reported as 7 to 12.8 hours. The exact mode of action of sulfur in the treatment of acne is unknown but it has been reported that it inhibits the growth of *Propionibacterium acnes* and the formation of free fatty acids.

INDICATIONS: Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS: Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is not to be used by patients with kidney disease.

WARNINGS: Although it is rare, sensitivity to sodium sulfacetamide may occur. Therefore, caution and careful supervision should be observed when prescribing this drug for patients who may be prone to hypersensitivity to topical sulfonamides. Systemic toxic reactions such as agranulocytosis, acute hemolytic anemia, purpura hemorrhagica, drug fever, jaundice, and contact dermatitis indicate hypersensitivity to sulfonamides. Particular caution should be employed if areas of denuded or abraded skin are involved.

FOR EXTERNAL USE ONLY. Keep away from eyes.

KEEP OUT OF REACH OF CHILDREN.

In case of accidental ingestion contact a poison control center immediately. Keep container tightly closed.

PRECAUTIONS: General: If irritation develops, use of the product should be discontinued and appropriate therapy instituted. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. The object of this therapy is to achieve desquamation without irritation, but sodium sulfacetamide and sulfur can cause reddening and scaling of the epidermis. These side effects are not unusual in the treatment of acne vulgaris, but patients should be cautioned about the possibility.

Information for Patients: Avoid contact with eyes, eyelids, lips and mucous membranes. If accidental contact occurs, rinse with water. If excessive irritation develops, discontinue use and consult your

physician.

Carcinogenesis, Mutagenesis and Impairment of Fertility:

Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy: Category C. Animal reproduction studies have not been conducted with Sodium Sulfacetamide 10% & Sulfur 5% Cleanser. It is also not known whether Sodium Sulfacetamide 10% & Sulfur 5% Cleanser can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Sulfacetamide 10% & Sulfur 5% Cleanser should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether sodium sulfacetamide is excreted in the human milk following topical use of Sodium Sulfacetamide 10% & Sulfur 5% Cleanser. However, small amounts of orally administered sulfonamides have milk. In view of this and because many drugs are excreted in human milk, caution should be exercised when Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children under the age of 12 have not been established.

ADVERSE REACTIONS: Although rare, sodium sulfacetamide may cause local irritation.

Call your doctor for medical advice about side effects.

DOSAGE AND ADMINISTRATION: Wash affected areas once or twice daily, or as directed by your physician. Avoid contact with eyes or mucous membranes. Wet skin and liberally apply to areas to be cleansed, massage gently into skin for 10-20 seconds working into a full lather, rinse thoroughly and pat dry. If drying occurs, it may be controlled by rinsing cleanser off sooner or using less often.

HOW SUPPLIED: Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is available in a 6 oz (170 g) bottle, NDC 42808-113-06 and a 12 oz (340 g) bottle, NDC 42808-113-12.

Store at 20 to 25°C (68 to 77°F). See USP Controlled Room Temperature. Protect from freezing.

Manufactured in the U.S.A. for
Exact-Rx, Inc., Melville, NY 11747

00-113-205-00

Iss:01

INDICATIONS: Sodium Sulfacetamide 10% and Sulfur 5% Cleanser is indicated for the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

DIRECTIONS FOR USE: Wash affected areas once or twice daily, or as directed by your physician. Avoid contact with eyes or mucous membranes. Wet skin and liberally apply to areas to be cleansed, massage gently into skin for 10-20 seconds working into a full lather, rinse thoroughly and pat dry. If drying occurs, it may be controlled by rinsing cleanser off sooner or using less often. **See label booklet for complete product information.**

FOR EXTERNAL USE ONLY. NOT FOR INTRAVAGINAL OR OPHTHALMIC USE. (KEEP AWAY FROM EYES)

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN: in case of accidental ingestion contact a poison control center immediately. Keep container tightly closed.

CONTRAINDICATIONS: Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is not to be used by patients with kidney disease.

CAUTION: If redness or irritation occurs, discontinue use.

Each gram of sodium sulfacetamide 10% and sulfur 5% cleanser contains 100 mg of sodium sulfacetamide and 50 mg of sulfur in a cleanser containing ammonium lauryl sulfate, butylated hydroxytoluene, cetyl alcohol, cocamidopropyl betaine, disodium EDTA, glycerin, glyceryl stearate SE, guar gum, methylparaben, PEG-100 stearate, propylene glycol, propylparaben, purified water, sodium thiosulfate, stearyl alcohol, triacetin.

Store at 20 to 25°C (68 to 77°F). See USP Controlled Room Temperature. Protect from freezing. See bottle for lot number and expiration date.

Important Note:

This bottle is not filled to the top but does contain 12 fl oz of product as identified on the front panel of the bottle.

Manufactured in the U.S.A. for
Exact-Rx, Inc., Melville, NY 11747

00-11312-200-01



3 42808 11312 5

NDC 42808-113-12

Rx Only

Sodium Sulfacetamide & Sulfur

(Sodium Sulfacetamide 10% & Sulfur 5%)



CLEANSER

Exact-Rx
INCORPORATED

Net Wt. 12 oz (340 g)

For External Use Only

Lift Here

NDC 42808-113-06

Rx Only

INDICATIONS: Sodium Sulfacetamide 10% and Sulfur 5% Cleanser is indicated for the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

DIRECTIONS FOR USE: Wash affected areas once or twice daily, or as directed by your physician. Avoid contact with eyes or mucous membranes. Wet skin and liberally apply to areas to be cleansed, massage gently into skin for 10-20 seconds working into a full lather, rinse thoroughly and pat dry. If drying occurs, it may be controlled by rinsing cleanser off sooner or using less often. See label booklet for complete product information.

FOR EXTERNAL USE ONLY. NOT FOR INTRAVAGINAL OR OPHTHALMIC USE. (KEEP AWAY FROM EYES)

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN: in case of accidental ingestion contact a poison control center immediately. Keep container tightly closed.

CONTRAINDICATIONS: Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is not to be used by patients with kidney disease.

CAUTION: If redness or irritation occurs, discontinue use.

Each gram of sodium sulfacetamide 10% and sulfur 5% cleanser contains 100 mg of sodium sulfacetamide and 50 mg of sulfur in a cleanser containing ammonium lauryl sulfate, butylated hydroxytoluene, cetyl alcohol, cocamidopropyl betaine, disodium EDTA, glycerin, glyceryl stearate SE, guar gum, methylparaben, PEG-100 stearate, propylene glycol, propylparaben, purified water, sodium thiosulfate, stearyl alcohol, triacetin.

Store at 20 to 25°C (68 to 77°F). See USP Controlled Room Temperature. Protect from freezing. See bottle for lot number and expiration date.

Important Note:

This bottle is not filled to the top but does contain 6 fl oz of product as identified on the front panel of the bottle.

Manufactured in the U.S.A. for
Exact-Rx, Inc., Melville, NY 11747
00-11306-200-01



Sodium Sulfacetamide & Sulfur

(Sodium Sulfacetamide 10% & Sulfur 5%)

10%/5%

CLEANSER

Exact-Rx
INCORPORATED

Net Wt. 6 oz (170 g)

EXACT-RX SODIUM SULFACETAMIDE AND SULFUR 10%/5% CLEANSER

sodium sulfacetamide, sulfur lotion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42808-113
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	50 mg in 1 g
SULFACETAMIDE SODIUM (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5)	SULFACETAMIDE SODIUM	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
GUAR GUM (UNII: E89I1637KE)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
TRIACETIN (UNII: XHX3C3X673)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42808-113-06	170 g in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2011	
2	NDC:42808-113-12	340 g in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/01/2011	

Labeler - Exact-Rx, Inc. (137953498)

Revised: 5/2020

Exact-Rx, Inc.